JUN 24 2010

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the DARCO® Headed Cannulated Screws.

A.1. Submitted By: Wright Medical Technology, Inc.
5677 Airline Rd
Arlington, TN 38002

Date: February 4, 2010

Contact Person: Kelsey Lee
Regulatory Affairs Specialist I
(901) 290-5909

A.2. Proprietary Name: **DARCO® Headed Cannulated Screws**

Common Name: Cannulated Bone Screw

Device Classification Regulation: 21 CFR 888.3040--Class II

Device Product Code & Panel: HWC: Screw, Fixation, Bone

A.3. Predicate Device: *aap* Cannulated Screws (K080101)

A.4. Device Description

The DARCO® Headed Cannulated Screws will be offered in various sizes, thread types, and lengths. The screws contain an optional washer will be made available with the system. The screws and washers are manufactured from titanium alloy.

The design features of the DARCO ® Headed Cannulated Screws are substantially equivalent to the design features of other devices previously cleared for market.

A.5. Intended Use

The DARCO® Headed Cannulated Screws are intended for use over a guide pin or wire for bone fracture fixation and bone fragment fixation. Wright Medical's washers may be used with the screws in cases where the patient has poor bone quality.

- Minimally invasive fracture / joint reconstructions
- Multiple- fragment joint fractures
- Simple metaphyseal fractures
- Simple epiphyseal fractures
  - Fractures of the head of the humerus
  - Fractures of the head of the tibia
  - Cooper fractures of the tibia
  - Fractures of the radius

- Fractures of the wrist, ankle, elbow and shoulder
- Scaphoid fractures and other fractures of the hand
- Metatarsal fractures and other fractures of the foot
- Ligament fixation of the proximal humerus
- Ligament avulsion injuries (Apohysis)
- Fractures of small joint bones
  - Malleolar fractures
  - Navicular fractures
- Fractures of the calcaneus and talus
- Arthrodesis of the ankle joint
- Avulsion fracture and metatarsal V
- Fractures of the tarsal region

The indications are limited in scope when compared to the legally marketed predicate device. Wright Medical Technology, Inc. has chosen to limit the indications to focus on the market in which the subject device is being promoted.

A.6. Technological Characteristics Comparison

The subject DARCO® Headed Cannulated Screws and the predicate *aap* Cannulated Screws have the following similarities: Materials, Diameters, Thread Types, Lengths, and Indications.

B.1. Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence was shown through the full characterization of the subject and predicate screws and the use of available complaint data.

The safety and effectiveness of the DARCO® Headed Cannulated Screws is adequately supported by the substantial equivalence information, materials information, and comparison of design characteristics provided within the Premarket Notification.

B.2. Substantial Equivalence – Clinical Evidence

N/A

B.3. Substantial Equivalence - Conclusions

Substantial equivalence is shown through the characterization of the subject and predicate screws and the available complaint data. The materials, diameters, lengths, thread types and indications are similar and there are no substantial differences between the subject and predicate. From the evidence given in the Premarket Notification, the subject screws can be expected to perform at least as well as the predicate screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

JUN 24 2010

Wright Medical Technology, Inc.
c/o Ms. Kelsey Lee
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K100359
Trade/Device Name: Darco® Headed Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 9, 2010
Received: June 10, 2010

Dear Ms. Lee,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100359

Device Name: DARCO® Headed Cannulated Screws

Indications For Use:

The DARCO® Headed Cannulated Screws are intended for use over a guide pin or wire for bone fracture fixation and bone fragment fixation. Wright Medical's washers may be used with the screws in cases where the patient has poor bone quality.

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  - Fractures of the radius
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- Scaphoid fractures and other fractures of the hand
- Metatarsal fractures and other fractures of the foot
- Ligament fixation of the proximal humerus
- Ligament avulsion injuries (Apohysis)
- Fractures of small joint bones
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- Fractures of the calcaneus and talus
- Arthrodesis of the ankle joint
- Avulsion fracture and metatarsal V
- Fractures of the tarsal region

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100359